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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,296	03/21/2001	Laura L. Kiessling	1-00	4642

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EXAMINER
BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
1639	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/815,296	Kiessling et al
Examiner	**Art Unit**
Maurie G. Baker, Ph.D.	1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *ONE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-141* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-141* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 (in part), 2-47, 56-95, 140 and 141, drawn to a method for inducing a biological response in a biological system *in vitro*, classified in various classes and/or subclasses depending on the compound used in the method, for example, any of classes 435, 436 or 530-570, subclasses various.

II. Claims 1 (in part) and 48-50, drawn to a method for inducing a biological response in a biological system *in vivo*, classified in various classes and/or subclasses depending on the compound used in the method, for example, any of classes 435, 436, 514 or 524, subclasses various.

III. Claim 51, drawn to a method for treating a bacterial infection where the multivalent ligand used for treatment comprises a plurality of signal recognition elements that are chemoattractant signals, classified in various classes and/or subclasses depending on the compound used for treatment, for example, any of classes 514 or 524, subclasses various.

IV. Claim 52, drawn to a pharmaceutical composition for treating a bacterial infection which comprises an amount of a multivalent ligand effective for inhibiting the chemotaxis response in the bacterium, classified in various classes and/or subclasses depending on the compound in the composition, for example, any of classes 514 or 524, subclasses various.

V. Claim 53, drawn to a method for modulating the chemotaxis response of a eukaryotic cell, classified in various classes and/or subclasses depending on the compound used in the method, for example, any of classes 435, 436 or 530-570, subclasses various.

VI. Claim 54, drawn to a method for treating an infection of a eukaryotic pathogen or parasite, classified in various classes and/or subclasses depending on the compound used for treatment, for example, any of classes 514 or 524, subclasses various.

VII. Claim 55, drawn to a pharmaceutical composition for treating an infection of a eukaryotic pathogen or parasite, classified in various classes and/or

subclasses depending on the compound in the composition, for example, any of classes 514 or 524, subclasses various.

VIII. Claims 96-115 and 129-131, drawn to a multivalent ligand, classified variously depending on the structure of the compound, for example, in class 548, subclasses 400+ or class 549, subclasses 29+ or 229+.

IX. Claims 116-121, drawn to a complex of multivalent ligand with one or more proteins, classified variously depending on the structure of the complex, for example, in class 530, subclasses 300+.

X. Claims 122-125 and 132, drawn to a method for enhancing aggregation of biological particles, classified in various classes and/or subclasses depending on the compound used in the method, for example, any of classes 435, 436 or 530-570, subclasses various.

XI. Claims 126-128, drawn to a method for inducing or enhancing induction of apoptosis in a cell, classified in various classes and/or subclasses depending on the compound used in the method, for example, any of classes 435, 436 or 530-570, subclasses various.

XII. Claims 133-139, drawn to a method for generating an assembly of biological macromolecules or particles, classified in various classes and/or subclasses depending on the compound used in the method, for example, any of classes 435, 436 or 530-570, subclasses various.

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I, II, III, V, VI, X, XI and XII are different methods. The methods are different because they use different steps, reagents and/or will produce different results/products. They therefore have different issues regarding patentability and enablement and represent patentably distinct subject matter. This is elaborated upon for the different Groups below.

4. In the instant case, the methods of Groups I & II differ from all other Groups as they are methods for inducing a biological response in a biological system. The methods of Groups I & II are different from each other as one is performed *in vitro* and the other *in vivo*. Groups III & VI differ from all other Groups as they are methods for treatment. The methods of Groups III & VI are different from each other as the condition treated in each method is different. The method of Group VI is different from all other Groups as it is a method for "modulating the chemotaxis response of a eukaryotic cell". The method of Group X is different from all other Groups as it is a method for "enhancing aggregation of biological particles". The method of Group XI is different from all other Groups as it is a method for "for inducing or enhancing induction of apoptosis in a cell". Finally, the method of Group XII is different from all other Groups as it is a method for "for generating an assembly of biological macromolecules or particles".

5. As described above, each method has a different end result and would also require different steps. Therefore, Groups I, II, III, V, VI, X, XI and XII represent patentably distinct methods.

6. Groups IV, VII, VIII and IX represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. Therefore, they have different issues regarding patentability and enablement and represent patentably distinct subject matter. In the instant case, the products of Groups IV & VII are pharmaceutical compositions, which are clearly different from a compound (multivalent ligand) or complex (i.e. Groups VIII and IX). The products of Groups IV & VII are different from each other are they

are pharmaceutical compositions for treating different conditions. The product of Group VIII is a compound (multivalent ligand) and the product of Group IX is a complex, which are clearly different in structure and function.

7. Groups VIII and I & II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the product of Group VIII could be used in the creation of combinatorial libraries or for structure-activity studies. Moreover, applicants themselves specifically claim at least two different methods of use for the product of Group VIII.

8. Groups IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product. That is, the infection of Group III could be treated with a wide variety of other products.

9. Groups VII and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product. That is, the infection of Group VI could be treated with a wide variety of other products.

10. The invention of Group IX does not appear to be related to any of the claimed methods. The inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects.

11. With respect to the methods of Groups V, X, XI and XII, it is unclear how these methods are related to any of the claimed products. If applicant argues that they are related to the product of Group VIII as processes of use and product, the following is noted. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product. For example, the product of Group VIII could be used in the creation of combinatorial libraries or for structure-activity studies. Moreover, applicants themselves specifically claim at least two different methods of use for the product of Group VIII.

12. Therefore, the groups that describe these inventions each have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group could support a separate patent.

13. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. Please note that even though some of these groups *could* be classified in the same class and/or subclass, this has no effect on the non-patent literature search. The different inventions would require completely different searches in these databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Election of Species

14. This application contains claims directed to patentably distinct species of the claimed invention for ***all of*** **Groups I –XII.** Election is required as follows.

15. If applicant elects the invention of **Group I**, applicant is required to elect from the following patentably distinct species. Claim 1 is generic. Election is required as delineated below. There are three species and election is required from *each*.

A. Species of "biological system" (all components)

A *single, specific* species of "biological system" should be elected, for purposes of search. All components thereof should be defined as follows:

A single type of cell and the biological response associated therewith should be clearly elected (also see B below).

B. Species of "biological response"

A *single, specific* species of "biological response" should be elected, for purposes of search, from the following:

B1. Chemotaxis, e.g. claim 6
B2. Biofilm formation, e.g. claim 11
B3. Nutrient uptake, e.g. claim 14
B4. Release of an intracellular signal, e.g. claim 28
B5. Immune response to an antigen or epitope, e.g. claim 44
B6. Cell migration, cell adhesion or formation of cell to cell junctions, e.g. claim 56

Also, whether the response is enhanced or prevented/inhibited should be elected.

C. Species of "multivalent ligand" used in the method

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

Additionally: Note that to be fully responsive to this requirement, a listing of all claims readable on the elected species should be provided (see paragraph 28 below).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

16. If applicant elects the invention of **Group II**, applicant is required to elect from the following patentably distinct species. Claim 1 is generic. Election is required as delineated below. There are three species and election is required from *each*.

A. Species of "biological system"

A *single, specific* species of "biological system" should be elected, for purposes of search.

B. Species of "biological response"

A *single, specific* species of "biological response" should be elected, for purposes of search. Also, whether the response is enhanced or prevented/inhibited should be elected.

C. Species of "multivalent ligand" used in the method

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

Additionally: Note that to be fully responsive to this requirement, a listing of all claims readable on the elected species should be provided (see paragraph 28 below).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

17. If applicant elects the invention of **Group III**, applicant is required to elect from the following patentably distinct species. Claim 51 is generic. Election is required as delineated below.

Species of "multivalent ligand" used in the method

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

18. If applicant elects the invention of **Group IV**, applicant is required to elect from the following patentably distinct species. Claim 52 is generic. Election is required as delineated below.

Species of "multivalent ligand" in the composition

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

19. If applicant elects the invention of **Group V**, applicant is required to elect from the following patentably distinct species. Claim 53 is generic. Election is required as delineated below.

Species of "multivalent ligand" used in the method

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

20. If applicant elects the invention of **Group VI**, applicant is required to elect from the following patentably distinct species. Claim 54 is generic. Election is required as delineated below.

Species of "multivalent ligand" used in the method

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

21. If applicant elects the invention of **Group VII**, applicant is required to elect from the following patentably distinct species. Claim 55 is generic. Election is required as delineated below.

Species of "multivalent ligand" in the composition

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

22. If applicant elects the invention of **Group VIII**, applicant is required to elect from the following patentably distinct species. Claim 96 is generic. Election is required as delineated below.

Species of "multivalent ligand"

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

Additionally: Note that to be fully responsive to this requirement, a listing of all claims readable on the elected species should be provided (see paragraph 28 below).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

23. If applicant elects the invention of **Group IX**, applicant is required to elect from the following patentably distinct species. Claim 116 is generic. Election is required as delineated below.

Species of complex

A *single, specific* species of "multivalent ligand" present in the complex should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*
Also, the protein present in the complex should be elected.

Additionally: Note that to be fully responsive to this requirement, a listing of all claims readable on the elected species should be provided (see paragraph 28 below).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

24. If applicant elects the invention of **Group X**, applicant is required to elect from the following patentably distinct species. Claim 122 is generic. Election is required as delineated below.

Species of "multivalent ligand" used in the method

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

Additionally: Note that to be fully responsive to this requirement, a listing of all claims readable on the elected species should be provided (see paragraph 28 below).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

25. If applicant elects the invention of **Group XI**, applicant is required to elect from the following patentably distinct species. Claim 126 is generic. Election is required as delineated below.

Species of "multivalent ligand" used in the method

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

Additionally: Note that to be fully responsive to this requirement, a listing of all claims readable on the elected species should be provided (see paragraph 28 below).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

26. If applicant elects the invention of **Group XII**, applicant is required to elect from the following patentably distinct species. Claim 133 is generic. Election is required as delineated below.

Species of "multivalent ligand" used in the method

A *single, specific* species of "multivalent ligand" should be elected, for purposes of search. All components thereof should be defined showing the signal recognition elements, molecular scaffold and all bonds between them. *A complete chemical structure (all atoms and bonds defined) should be elected.*

Additionally: Note that to be fully responsive to this requirement, a listing of all claims readable on the elected species should be provided (see paragraph 28 below).

The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made and/or in their specific steps and elements needed for carrying them out. Therefore, the species have different issues regarding patentability and represent patentably distinct subject matter. The different species would require different searches, thus creating an undue search burden.

27. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

28. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and ***a listing of all claims readable thereon***, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

29. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

30. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

31. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

32. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

33. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

34. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

35. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
August 15, 2003

MAURIE GARCIA BAKER PH.D
PRIMARY EXAMINER